# COMPLETE ALLERGY- diphenhydramine hcl tablet, film coated Chain Drug Consortium

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Premier Value 44-329

#### Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

#### **Purpose**

Antihistamine

#### Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - itchy, watery eyes
  - sneezing
  - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

### **Warnings**

#### Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

### Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

## Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

#### When using this product

- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

| adults and children 12 years and over | 1 to 2 tablets |
|---------------------------------------|----------------|
| children 6 to under 12                |                |
| years                                 | 1 tablet       |
| children under 6 vears                | do not use     |

#### Other information

- each tablet contains: calcium 30 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see end flap for expiration date and lot number

#### **Inactive ingredients**

corn starch, D&C red #27 aluminum lake, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

#### **Questions or comments?**

1-800-426-9391

## **Principal Display Panel**

**Premier** 

Value<sup>®</sup>

# \*COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL® ALLERGY ULTRATAB® TABLETS

#### **Complete Allergy**

Diphenhydramine HCl, 25 mg

#### **ANTIHISTAMINE**

Allergy relief for:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat

Easy to swallow

200 Tablets

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the

registered trademark Benadryl $^{\mathbb{R}}$  Allergy ULTRATAB $^{\mathbb{R}}$  Tablets. 50844 ORG101632906

Distributed By: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



Premier Value 44-329

diphenhydramine hcl tablet, film coated

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68016-641 |
| Route of Administration | ORAL           |                    |               |

| l | Active Ingredient/Active Moiety   |                                  |          |
|---|---|----------------------------------|----------|
| l | Ingredient Name   | Basis of Strength                | Strength |
| l | $\label{eq:diphenhydramine} \textbf{DIPHENHYDRAMINE HYDRO CHLO RIDE} \ (\text{UNII: } \text{TC2D6JAD40} \ ) \ (\text{DIPHENHYDRAMINE -UNII: } \text{8GTS82S83M})$ | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 25 mg    |

| Inactive Ingredients                                       |          |
|--|----------|
| Ingredient Name  | Strength |
| STARCH, CORN (UNII: O8232NY3SJ)                            |          |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS 185U6K)              |          |
| CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J) |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                      |          |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)            |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)        |          |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)                       |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                            |          |
| TALC (UNII: 7SEV7J4R1U)                                    |          |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)                      |          |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)          |          |

| Product Characteristics |      |              |          |  |
|-------------------------|------|--------------|----------|--|
| Color                   | PINK | Score        | no score |  |
| Shape                   | OVAL | Size         | 11mm     |  |
| Flavor                  |      | Imprint Code | 44;329   |  |
| Contains                |      |              |          |  |

| P | ackaging         |   |                             |                           |
|---|------------------|---|-----------------------------|---------------------------|
| # | Item Code        | Package Description                                     | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 | NDC:68016-641-24 | 2 in 1 CARTON   | 03/02/1990                  |                           |
| 1 |                  | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product |                             |                           |
| 2 | NDC:68016-641-10 | 1 in 1 CARTON   | 03/02/1990                  |                           |
| 2 |                  | 100 in 1 BOTTLE; Type 0: Not a Combination Product      |                             |                           |
| 3 | NDC:68016-641-00 | 1 in 1 CARTON   | 03/02/1990                  |                           |
| 3 |                  | 200 in 1 BOTTLE; Type 0: Not a Combination Product      |                             |                           |

| <b>Marketing Inform</b> | nation                                   |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |

| OTC MONOGRAPH FINAL | part341 | 03/02/1990 |  |
|---------------------|---------|------------|--|
|                     |         |            |  |

## Labeler - Chain Drug Consortium (101668460)

| Establishment           |         |           |                     |
|-------------------------|---------|-----------|---------------------|
| Name                    | Address | ID/FEI    | Business Operations |
| LNK International, Inc. |         | 038154464 | PACK(68016-641)     |

| Establishment           |         |           |                        |
|-------------------------|---------|-----------|------------------------|
| Name                    | Address | ID/FEI    | Business Operations    |
| LNK International, Inc. |         | 832867894 | MANUFACTURE(68016-641) |

| Establishment           |         |           |   |
|-------------------------|---------|-----------|---|
| Name                    | Address | ID/FEI    | Business Operations                     |
| LNK International, Inc. |         | 868734088 | MANUFACTURE(68016-641), PACK(68016-641) |

| Establishment           |         |           |                     |
|-------------------------|---------|-----------|---------------------|
| Name                    | Address | ID/FEI    | Business Operations |
| LNK International, Inc. |         | 967626305 | PACK(68016-641)     |

| Establishment           |         |           |                     |
|-------------------------|---------|-----------|---------------------|
| Name                    | Address | ID/FEI    | Business Operations |
| LNK International, Inc. |         | 832867837 | PACK(68016-641)     |

Revised: 11/2020 Chain Drug Consortium